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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,423	11/28/2001	Kimberly A. Gillis	102729-12	6433

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/997,423

Applicant(s)

GILLIS ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 October 2003 and 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 21-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 0603; 1003.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date part of 0304.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **FINAL REJECTION**

1. This action is in response to the Amendment and Response filed October 8, 2003, to the Response to Notice of Non-Compliant Amendment filed December 22, 2003, and to the Response to Notice of Non-Compliant Amendment filed March 11, 2004. Claims 1 and 16-20 have been amended, and claims 1-20 are now under consideration. Claims 21-34 remain withdrawn from consideration. Applicants' amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restriction***

3. It is again noted that claims 21-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the Response of April 25, 2003.

### ***Information Disclosure Statement***

4. Regarding the Information Disclosure Statement (IDS) filed June 24, 2003, it is noted that the IDS was entered into the application file after the mailing of the Office Action of July 8, 2003, but was filed prior to the mailing of that Office action. The references cited have been considered, and an initialed and signed copy of the 1449

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provided by Applicants is enclosed herewith. Regarding the foreign patent documents identified as BN, BO, and BP, it is further noted that the particular page numbers listed on the 1449 constitute the pages provided in the IDS and considered by the examiner (i.e., the complete documents were not cited or provided).

5. Regarding the IDS filed October 8, 2003, it is acknowledged that the IDS is a duplicate of an IDS previously filed by Applicant on February 27, 2002. It is further noted that the references originally filed by Applicant with the IDS of February 2002 were apparently misplaced by the Office, as those references (as well as the duplicate copies filed in October 2003) have now been entered into the application file. The references cited have been considered, and an initialed and signed copy of the 1449 provided by Applicants is enclosed herewith.

#### ***Specification***

6. It is noted that Applicants' amendments have overcome the objection to the specification related to embedded hyperlinks. Applicant has also amended the specification so as to properly capitalize trademarks, and so as to provide a descriptive title for the elected invention.

#### ***Claim Objections/Claim Rejections - 35 USC § 112***

7. In view of the amendment of claims 17-20 to provide proper claim dependency, the objection to claims 17-20 and the rejection of claims 17-20 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph are withdrawn.

***Claim Rejections - 35 USC § 112, first paragraph***

8. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of assessing whether a human subject has prostate cancer and methods for monitoring the progression of prostate cancer in a human subject in which increased levels of FKBP54 expression products are detected, does not reasonably provide enablement for methods of detecting or monitoring prostate cancer by detecting any type of change in expression levels. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for reasons set forth in the Office action of July 8, 2003.

It is first noted that Applicants' amendment to the claims have overcome the instant rejection in part. Specifically, the claims have been amended such that they are now limited to human subjects, as well as to a particular FKBP marker, FKBP54. However, the claims remain sufficiently broad so as to encompass detection of any type of change in the levels of FKBP54 expression products as an indicator of prostate cancer (claims 1-15) or as an indicator of prostate cancer progression (claims 16-20). The aspects of the rejection of July 8, 2003 that have not been overcome are summarized in the following paragraph.

As was discussed in the Office action of July 8, 2003, it is unpredictable as to whether one of skill in the art could use applicant's invention in a manner reasonably commensurate with the claims. The teachings of the specification provide sufficient evidence to establish that a particular FKBP marker, FKBP54, is expressed at higher

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levels in at least some types of prostate cancers as compared to healthy prostate tissue in human subjects (see, e.g., page 92), and that both PSA and FKBP54 expression increases in response to androgen treatment in a known model of androgen dependent prostate cancer (see, e.g., pages 81-92). However, the instant claims are not limited to methods in which an increase in expression is considered to be indicative of cancer or cancer progression. Rather, the claims are sufficiently broad so as to encompass the detection of any difference in the levels of expression of FKBP54 as an indicator of cancer or cancer progression. Accordingly, the claims encompass both decreases and increases in levels of marker expression (whereas applicant's data indicates that only increased expression is associated with cancer). Lacking guidance from the specification, one of skill in the art may look to the teachings of the art for additional guidance and enablement of a claimed invention. However, in the instant case, the prior art is silent with respect to any association between a decrease in FKBP54 expression and prostate cancer occurrence or progression. Accordingly, while the teachings of the specification are sufficient to enable one of skill in the art to practice methods of assessing whether a human subject has prostate cancer and methods for monitoring the progression of prostate cancer in a human subject in which increased levels of FKBP54 expression products are detected, it would require undue experimentation to use applicant's invention as claimed.

While Applicant has amended the claims to overcome this rejection in part (as discussed above), and has made reference to those particular amendments at page 4 of the Response of October 8, 2003, Applicant did not traverse the rejection with

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respect to the aspects of the rejection discussed above (i.e., enablement of any type of change in expression levels), and did not amend the claims so as to overcome the rejection. Accordingly, this rejection is maintained.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long, sweeping horizontal line that extends to the right.

Diana B. Johannsen  
Patent Examiner  
March 11, 2004